

# FIGURE 1

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## Once-Weekly Eprex® alpha Increases Hemoglobin and Decreases Ribavirin Dose Reductions Among HCV-Infected Patients Who Develop Anemia on Ribavirin/Interferon alpha-2b Therapy

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### ABSTRACT

**Background:** Anemia is a major side effect of ribavirin therapy in patients with chronic hepatitis C virus (HCV) infection. The purpose of this study was to evaluate the effect of once-weekly Eprex® (epoetin alfa) on hemoglobin levels and ribavirin dose reductions in HCV-infected patients who develop anemia on ribavirin/interferon alpha-2b therapy. **Methods:** A total of 100 HCV-infected patients who had been treated with ribavirin/interferon alpha-2b therapy for at least 12 weeks and who had developed anemia (hemoglobin < 10 g/dL) were randomized to receive either Eprex or placebo. The primary endpoint was the change in hemoglobin levels at 12 weeks. **Results:** The Eprex group had a significantly greater increase in hemoglobin levels compared to the placebo group. Additionally, the Eprex group had a significantly lower rate of ribavirin dose reductions compared to the placebo group. **Conclusions:** Once-weekly Eprex significantly increases hemoglobin levels and decreases ribavirin dose reductions in HCV-infected patients who develop anemia on ribavirin/interferon alpha-2b therapy.

### INTRODUCTION

Chronic hepatitis C virus (HCV) infection is a leading cause of liver disease and is associated with a high rate of morbidity and mortality. One of the major complications of HCV infection is anemia, which is caused by a combination of factors including decreased erythropoietin production, increased destruction of red blood cells, and decreased iron absorption. The purpose of this study was to evaluate the effect of once-weekly Eprex (epoetin alfa) on hemoglobin levels and ribavirin dose reductions in HCV-infected patients who develop anemia on ribavirin/interferon alpha-2b therapy.

### METHODS

**Study Design:** This was a randomized, controlled trial. **Patients:** A total of 100 HCV-infected patients who had been treated with ribavirin/interferon alpha-2b therapy for at least 12 weeks and who had developed anemia (hemoglobin < 10 g/dL) were randomized to receive either Eprex or placebo. **Interventions:** The Eprex group received 1500 IU of epoetin alfa once weekly, while the placebo group received a placebo injection. **Measurements and Main Results:** The primary endpoint was the change in hemoglobin levels at 12 weeks. The Eprex group had a significantly greater increase in hemoglobin levels compared to the placebo group. Additionally, the Eprex group had a significantly lower rate of ribavirin dose reductions compared to the placebo group.

### RESULTS

The Eprex group had a significantly greater increase in hemoglobin levels compared to the placebo group at 12 weeks. Additionally, the Eprex group had a significantly lower rate of ribavirin dose reductions compared to the placebo group. The results of this study suggest that once-weekly Eprex is an effective treatment for anemia in HCV-infected patients who are receiving ribavirin/interferon alpha-2b therapy.

### CONCLUSIONS

Once-weekly Eprex significantly increases hemoglobin levels and decreases ribavirin dose reductions in HCV-infected patients who develop anemia on ribavirin/interferon alpha-2b therapy. These findings suggest that Eprex may be a useful adjunctive therapy in the management of anemia in this patient population.

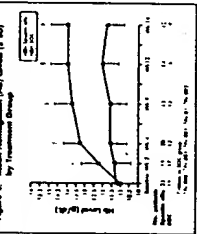
### DISCUSSION

The results of this study are consistent with previous findings that epoetin alfa can effectively increase hemoglobin levels in patients with anemia. The use of Eprex in HCV-infected patients who develop anemia on ribavirin/interferon alpha-2b therapy may allow for higher doses of ribavirin to be administered, which could potentially improve viral clearance and long-term outcomes.

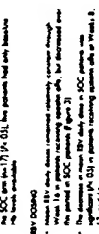
### REFERENCES

1. Westerman R, Bruu N, Hossain T, et al. Once-weekly Eprex increases hemoglobin and decreases ribavirin dose reductions in HCV-infected patients. *Ann Intern Med*. 2000;132:829-834.
2. Hossain T, Westerman R, Bruu N, et al. Efficacy and safety of once-weekly Eprex in HCV-infected patients. *J Hepatol*. 2001;34:101-107.
3. Dieterich D, Hossain T, Westerman R, et al. Hemoglobin levels and ribavirin dose reductions in HCV-infected patients. *Am J Med*. 2001;110:101-107.

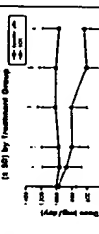
### FIGURE 1. Study design.



### FIGURE 2. Mean hemoglobin (g/dL) levels (± SD) by treatment group.



### FIGURE 3. Mean hemoglobin (g/dL) levels (± SD) by treatment group.



### CONCLUSIONS

Once-weekly Eprex significantly increases hemoglobin levels and decreases ribavirin dose reductions in HCV-infected patients who develop anemia on ribavirin/interferon alpha-2b therapy. These findings suggest that Eprex may be a useful adjunctive therapy in the management of anemia in this patient population.

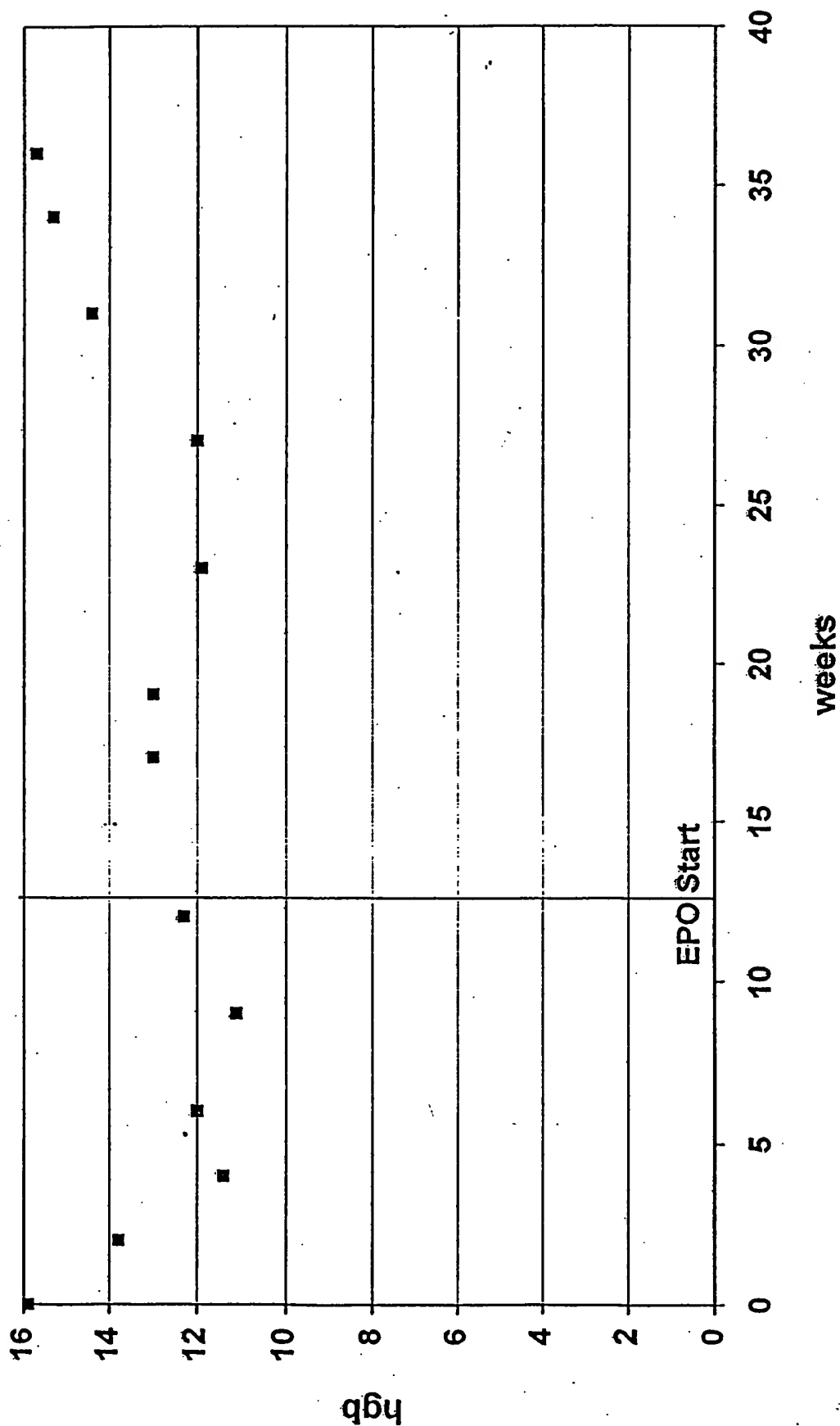
### ACKNOWLEDGMENTS

The authors thank the following individuals for their contributions to this study: [Names of individuals].

FOI25070429860

Figure 2.1

Subject #2



FOI250-10429850

### Subject #3

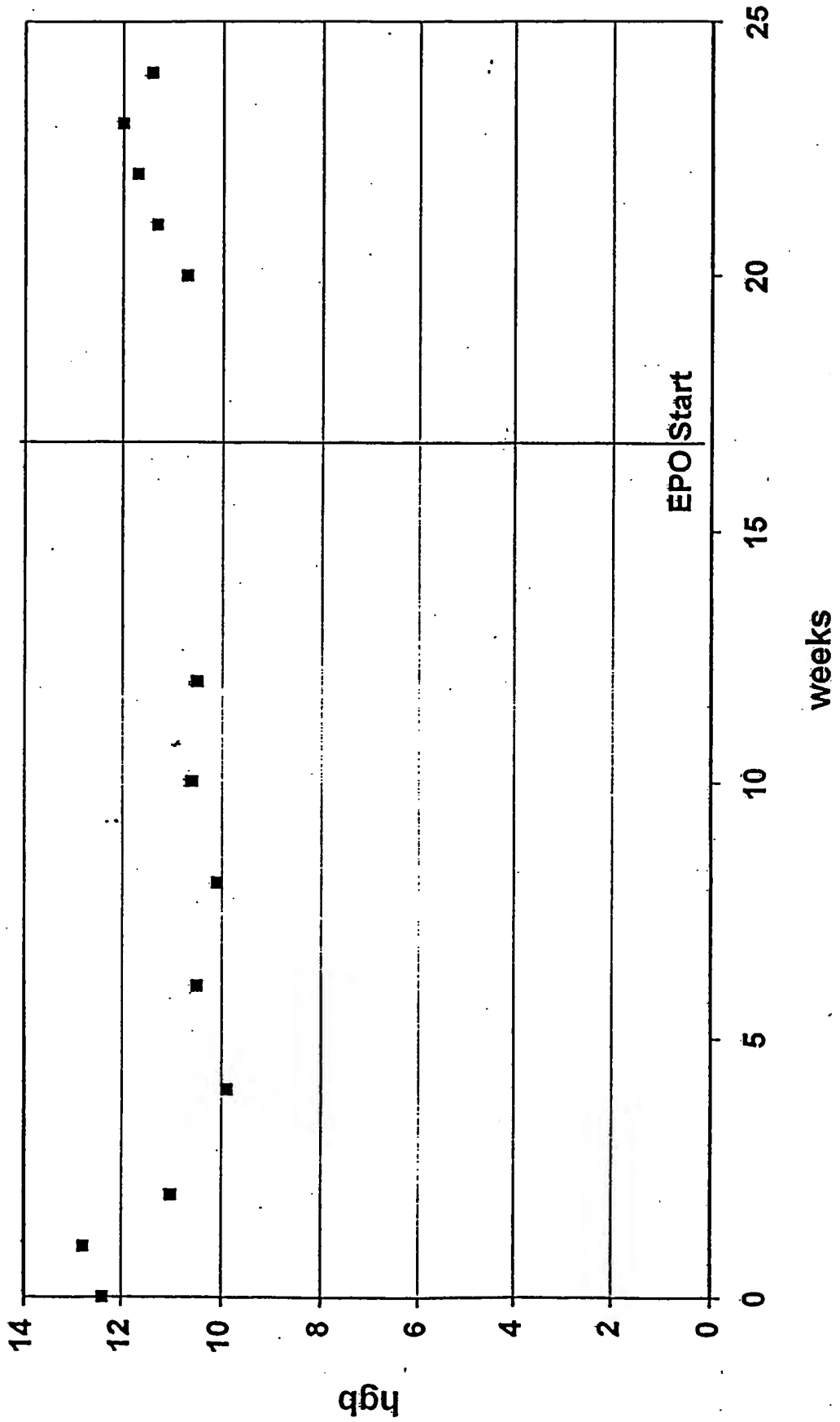


FIGURE 2.2

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FIGURE 3

Subject #4

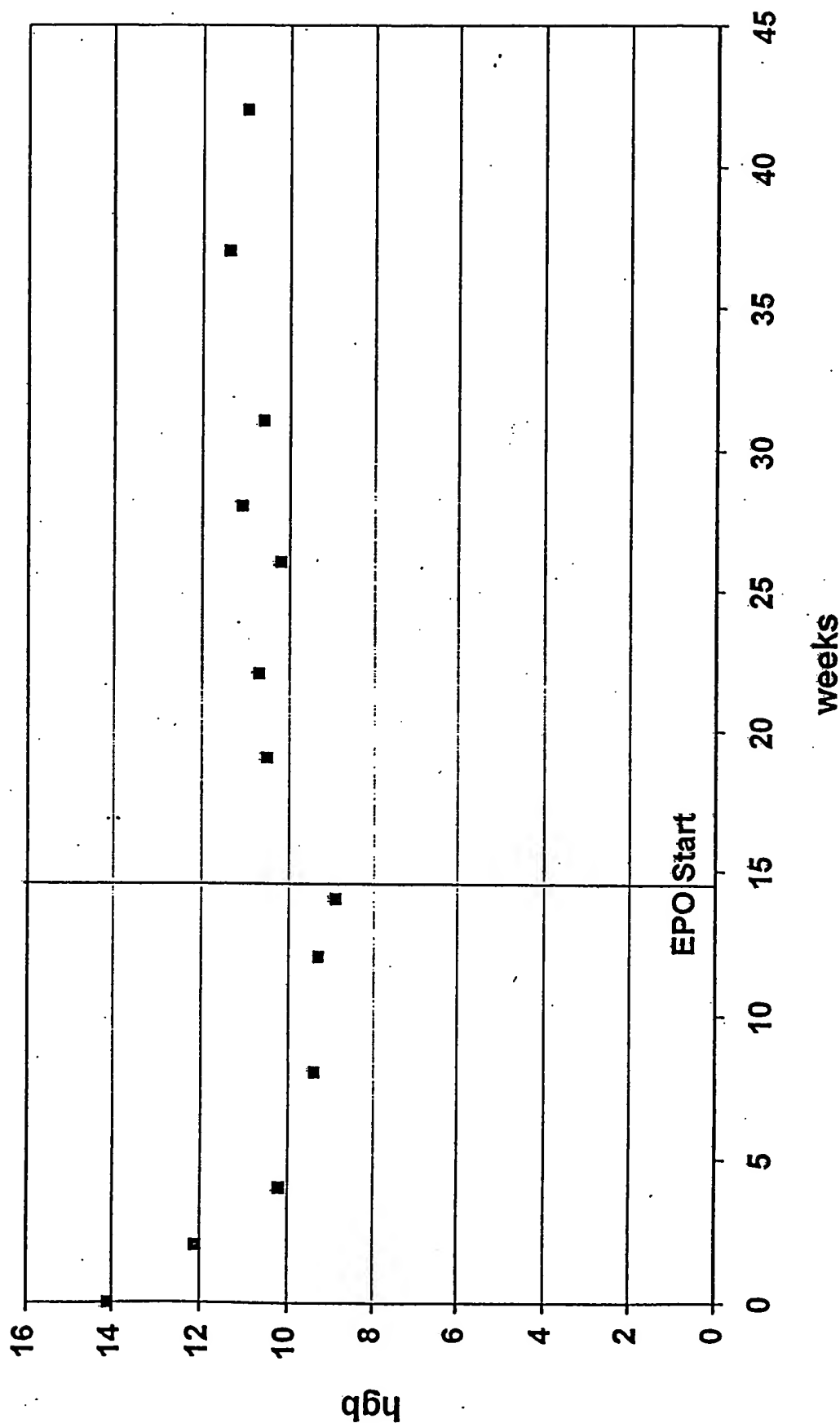
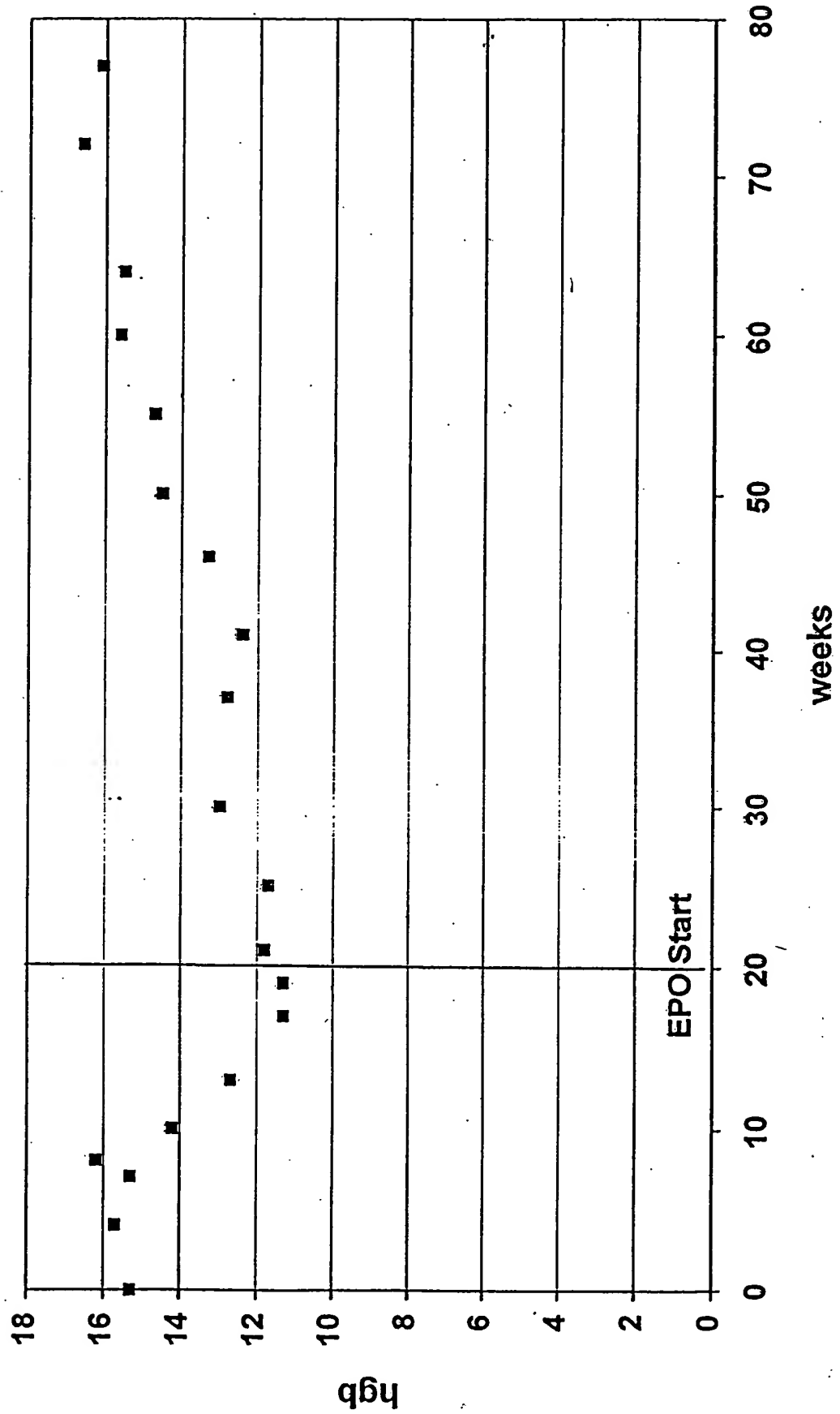


FIGURE 2.4

Subject #5



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# Subject #6

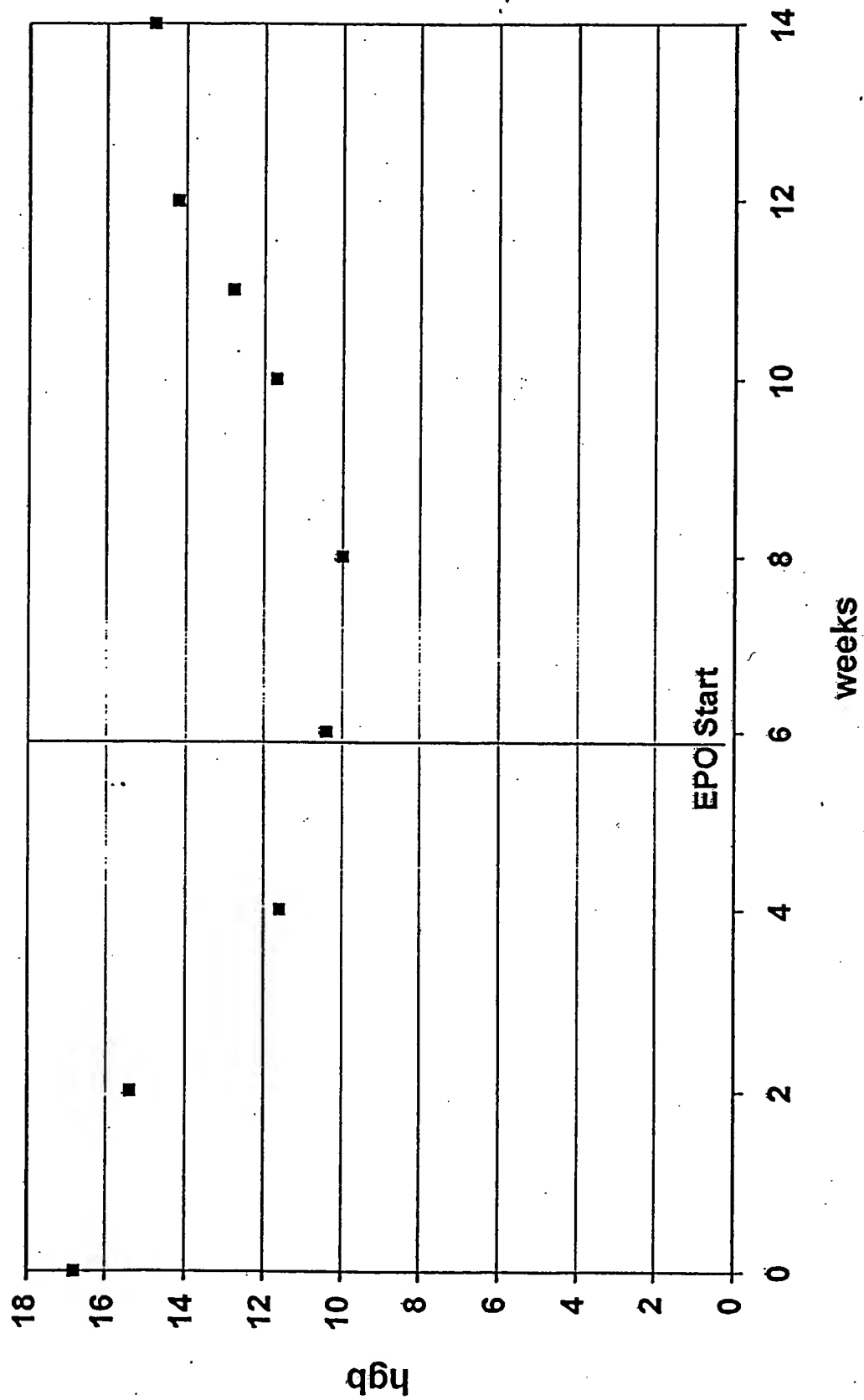
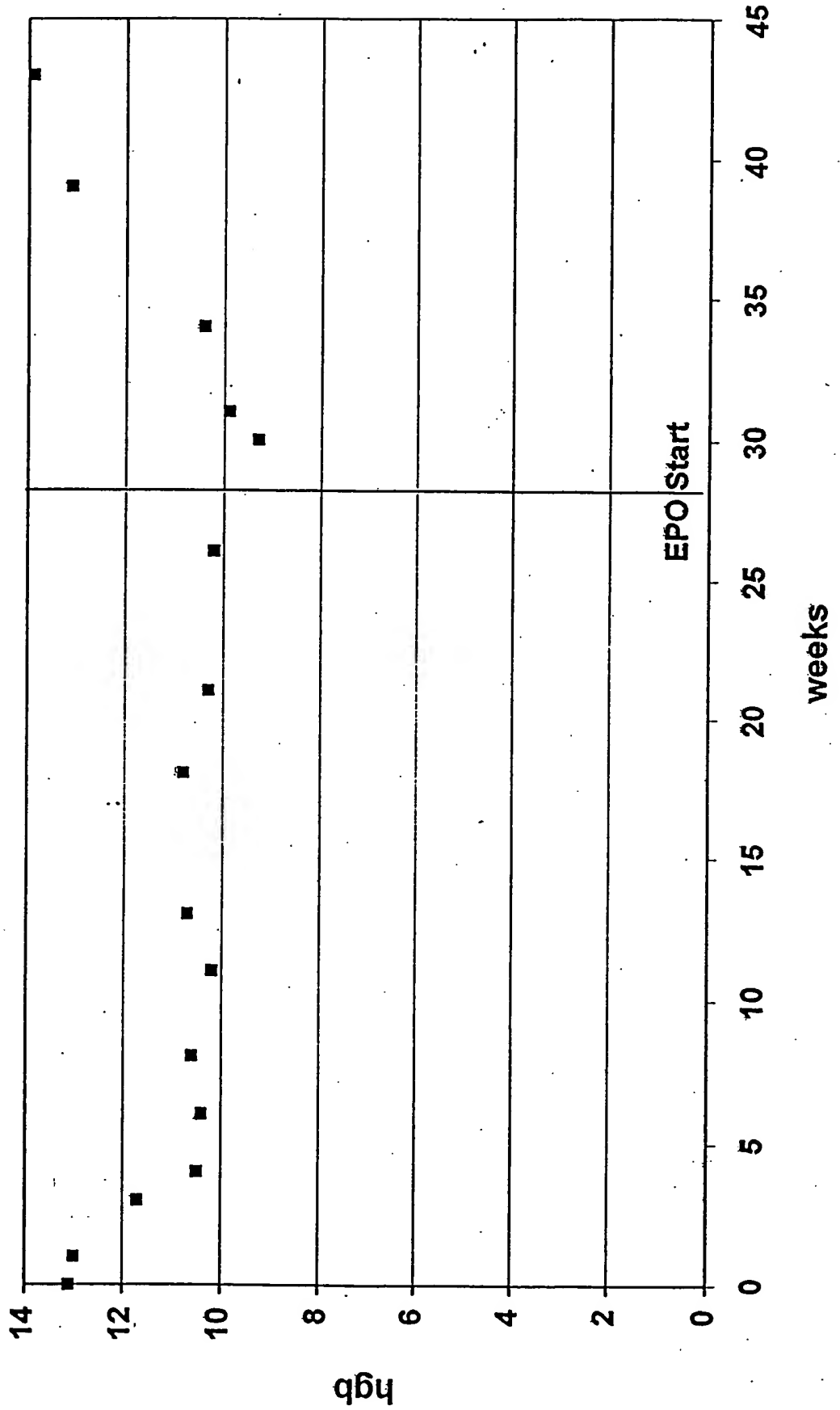


FIGURE 2.5

Subject #7

FIGURE 2.6



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# Subject #8

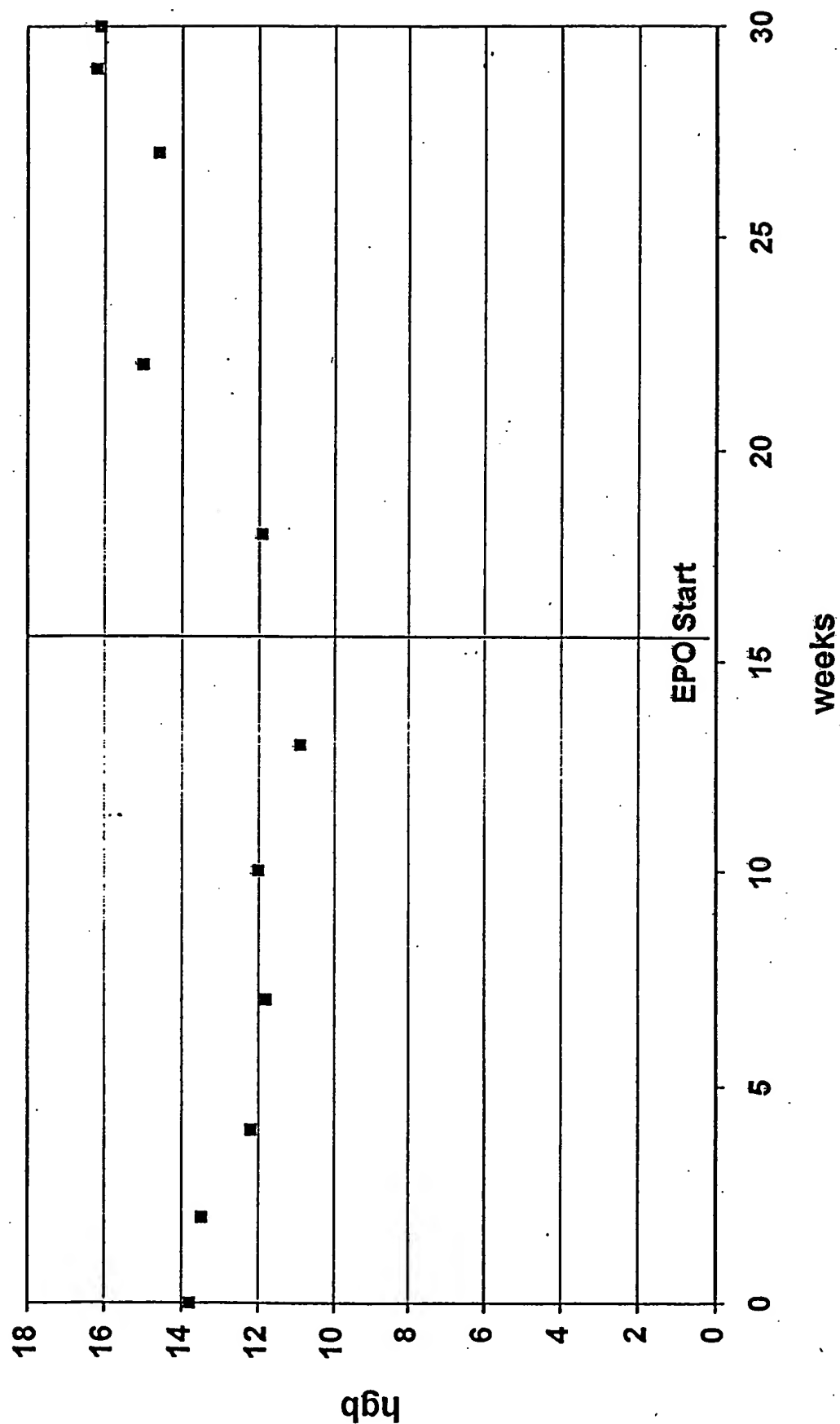


FIGURE 2.7



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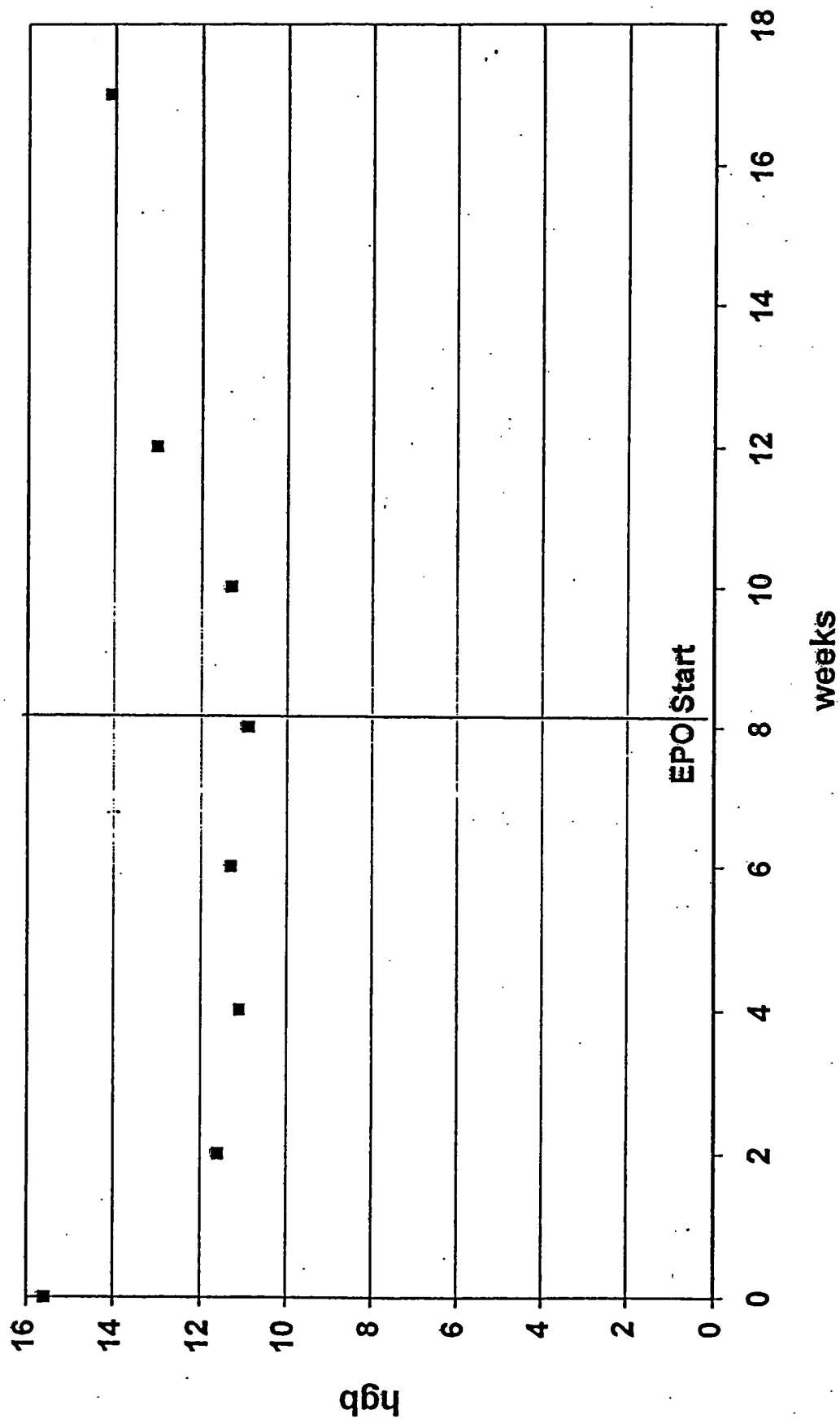
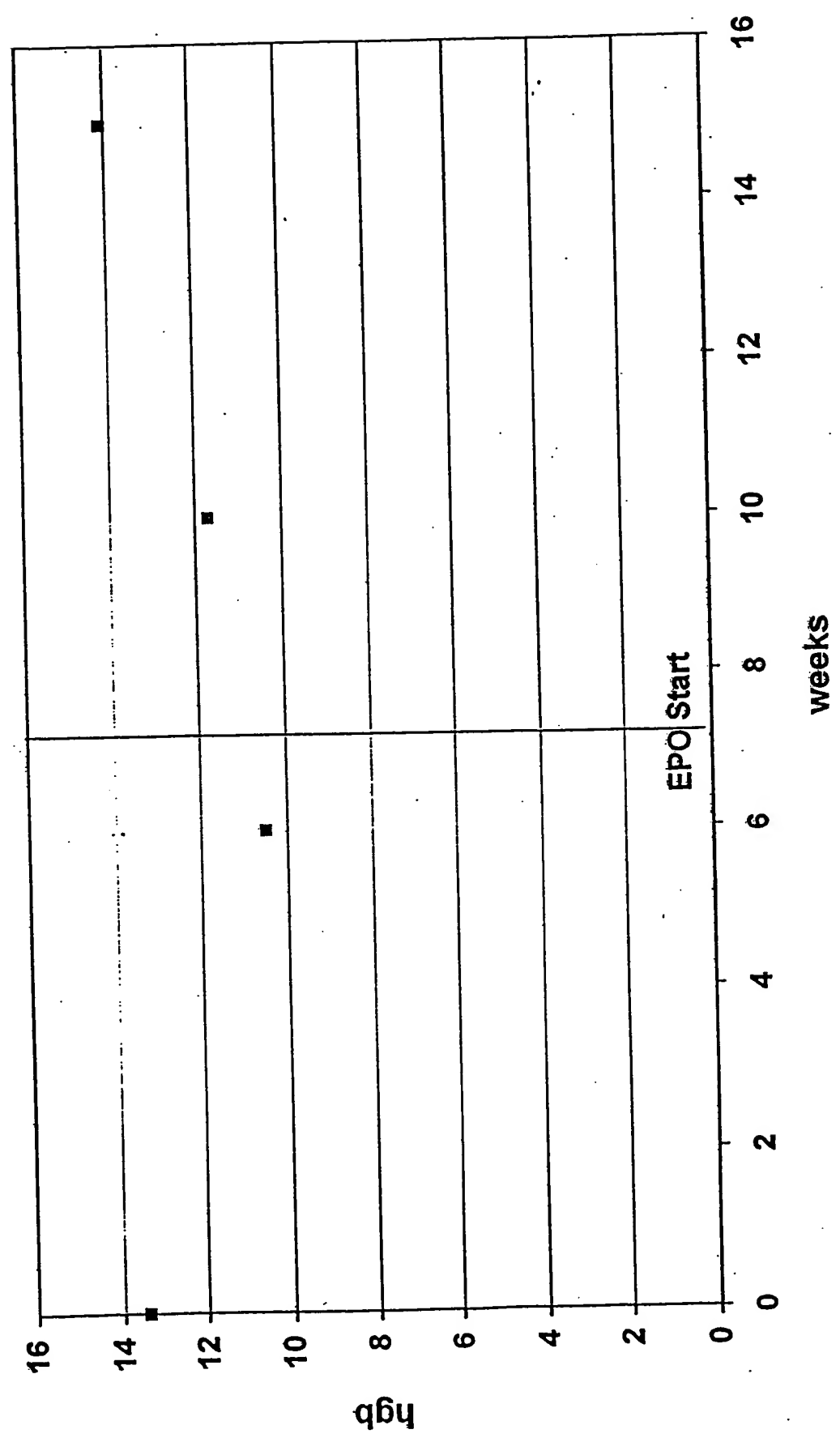


FIGURE 2.8

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# Subject #13

FIGURE 9



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# Subject #14

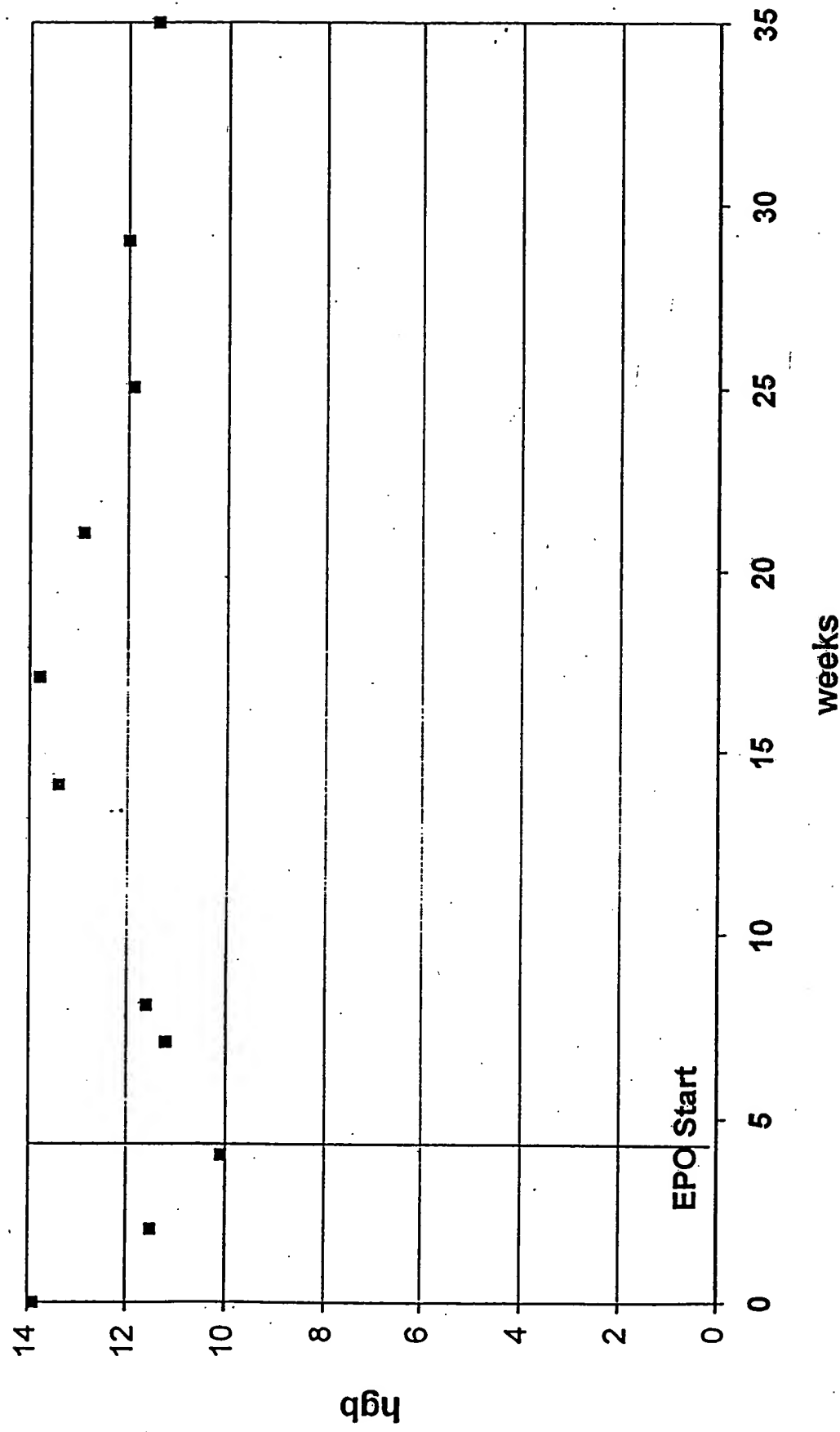
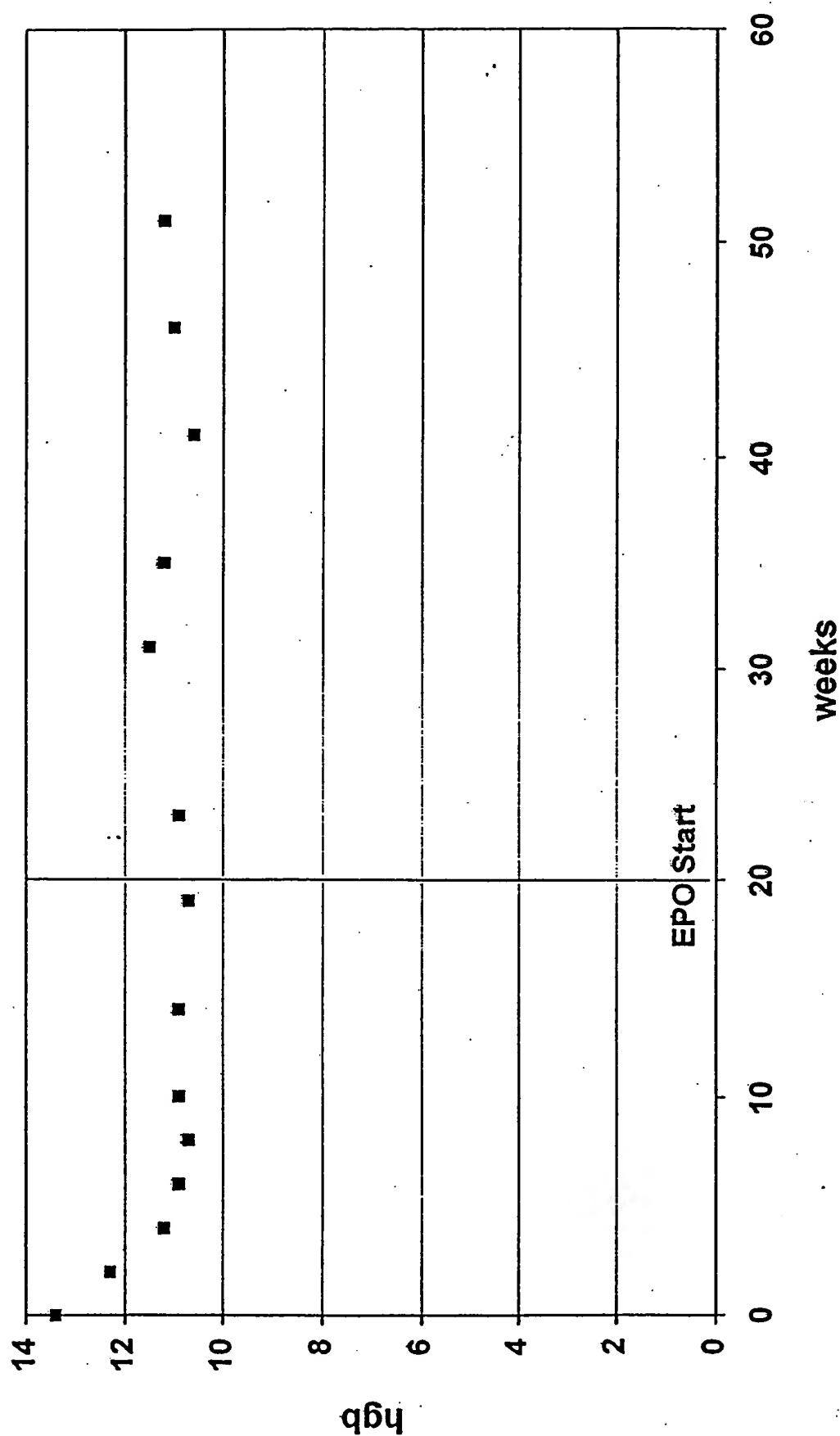


FIGURE 2.10

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# Subject #15



T0F250-40429860

# Subject #16

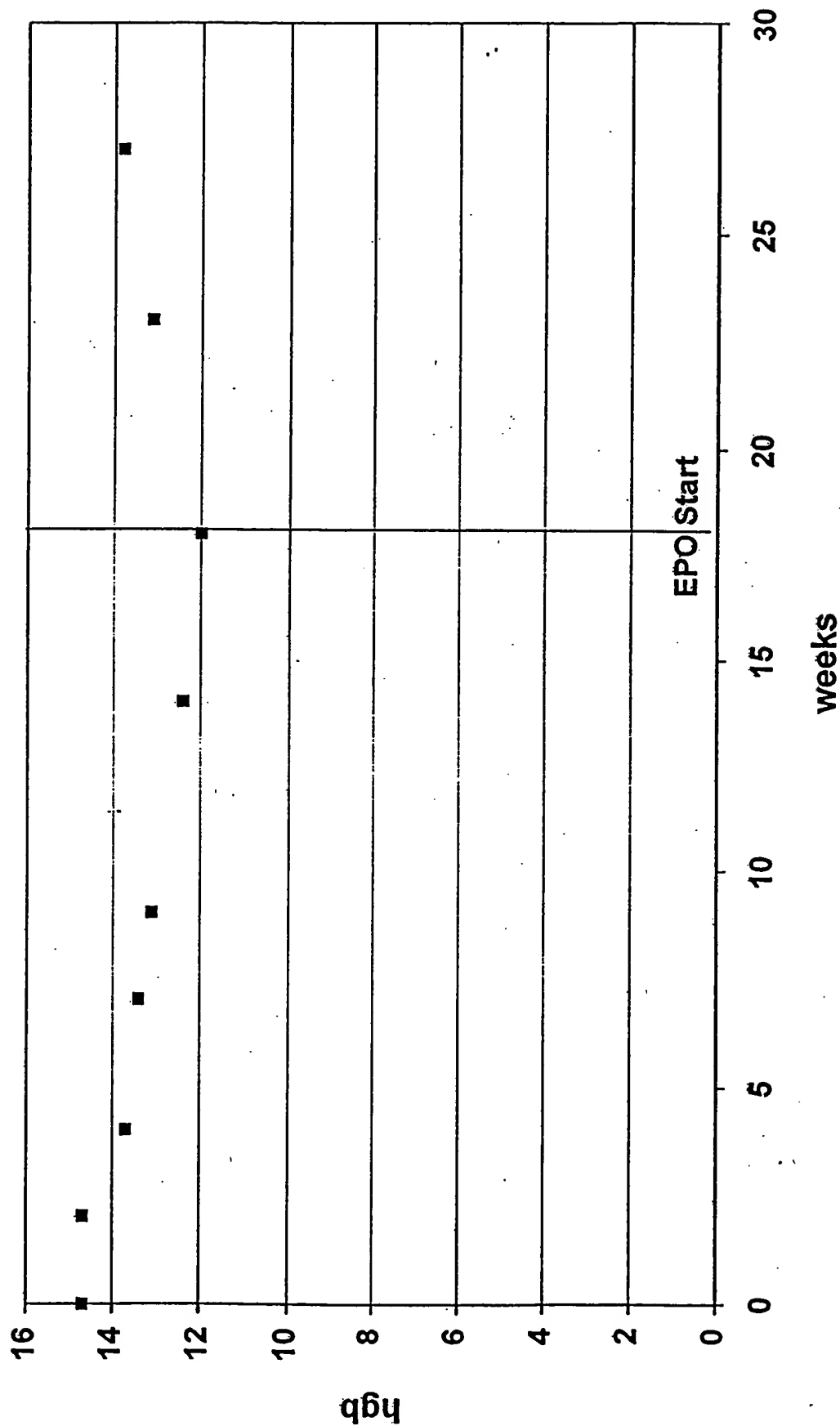
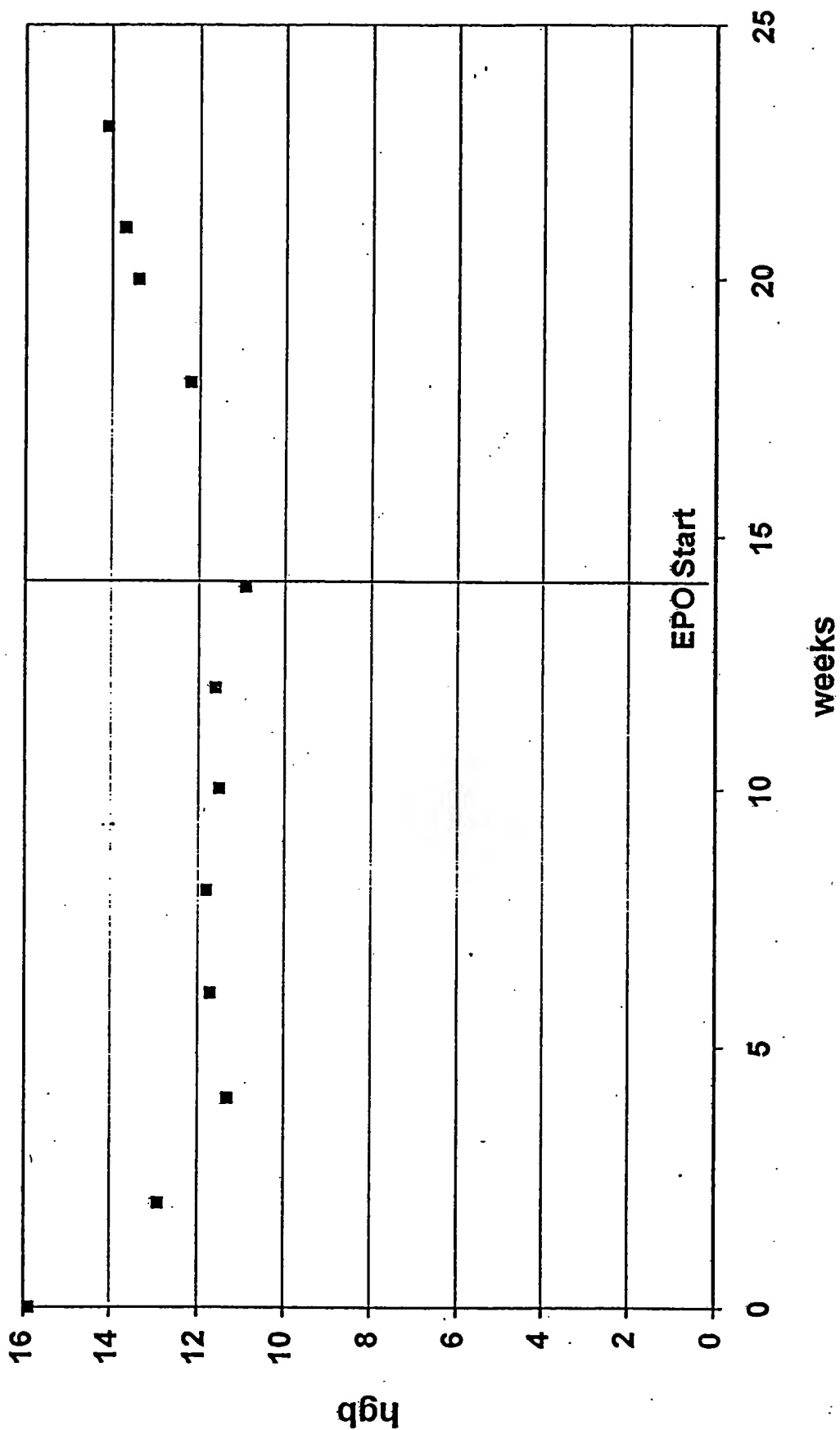


FIGURE 2.12

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FIGURE 2.13

Subject #18



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# Subject #19

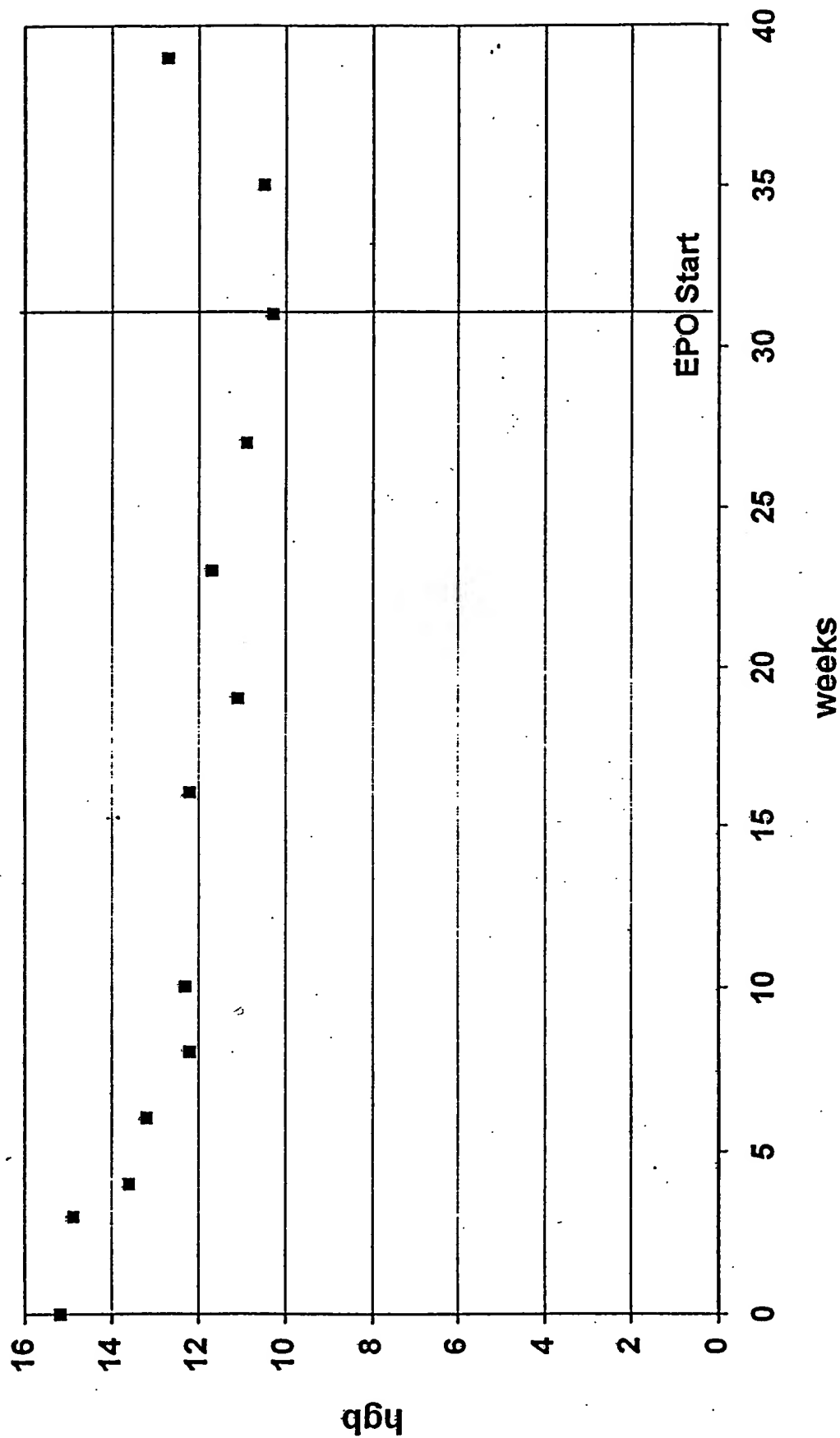
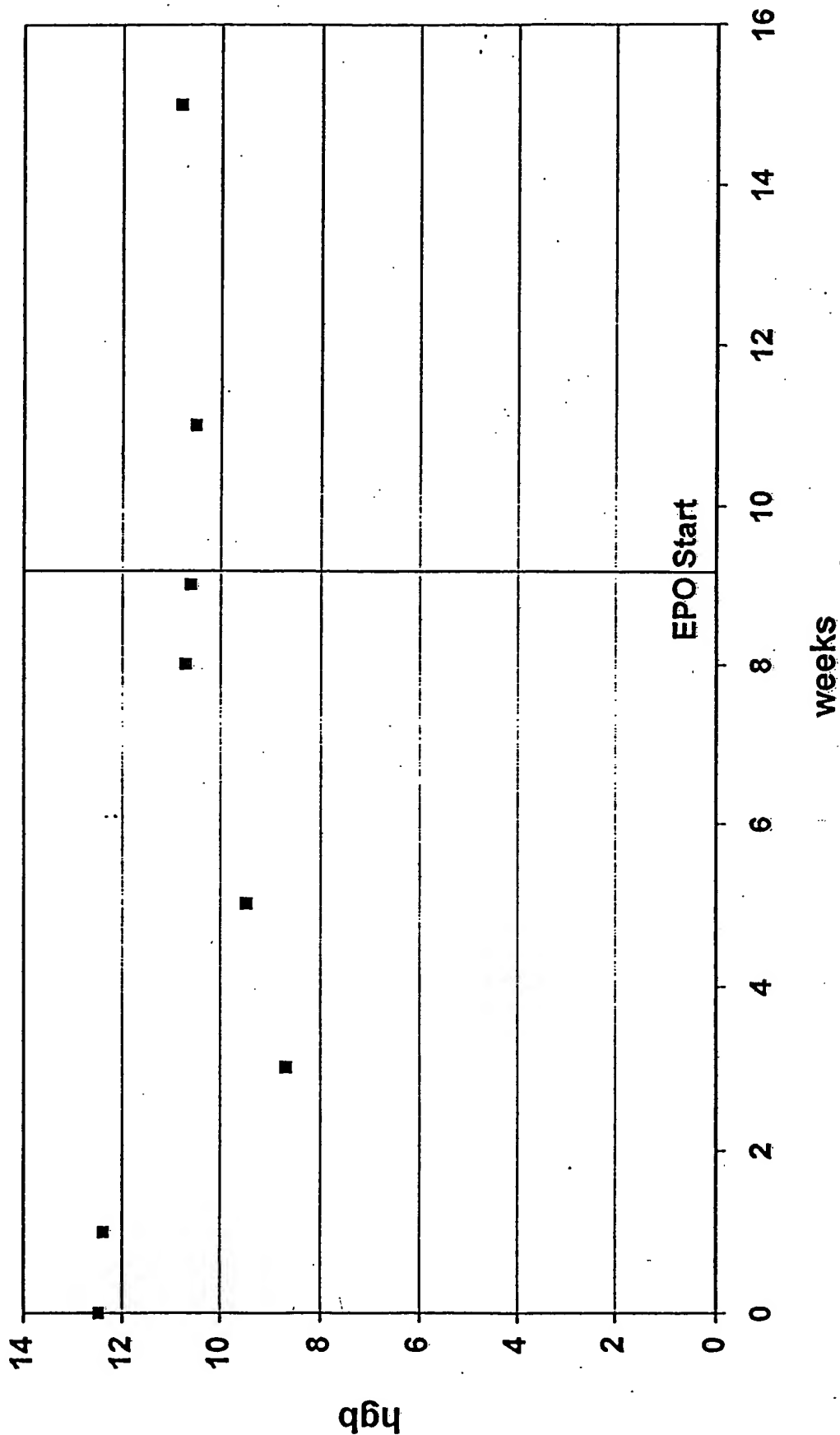


FIGURE 2.14

# Subject #20

FIGURE 2.15





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# Subject #21

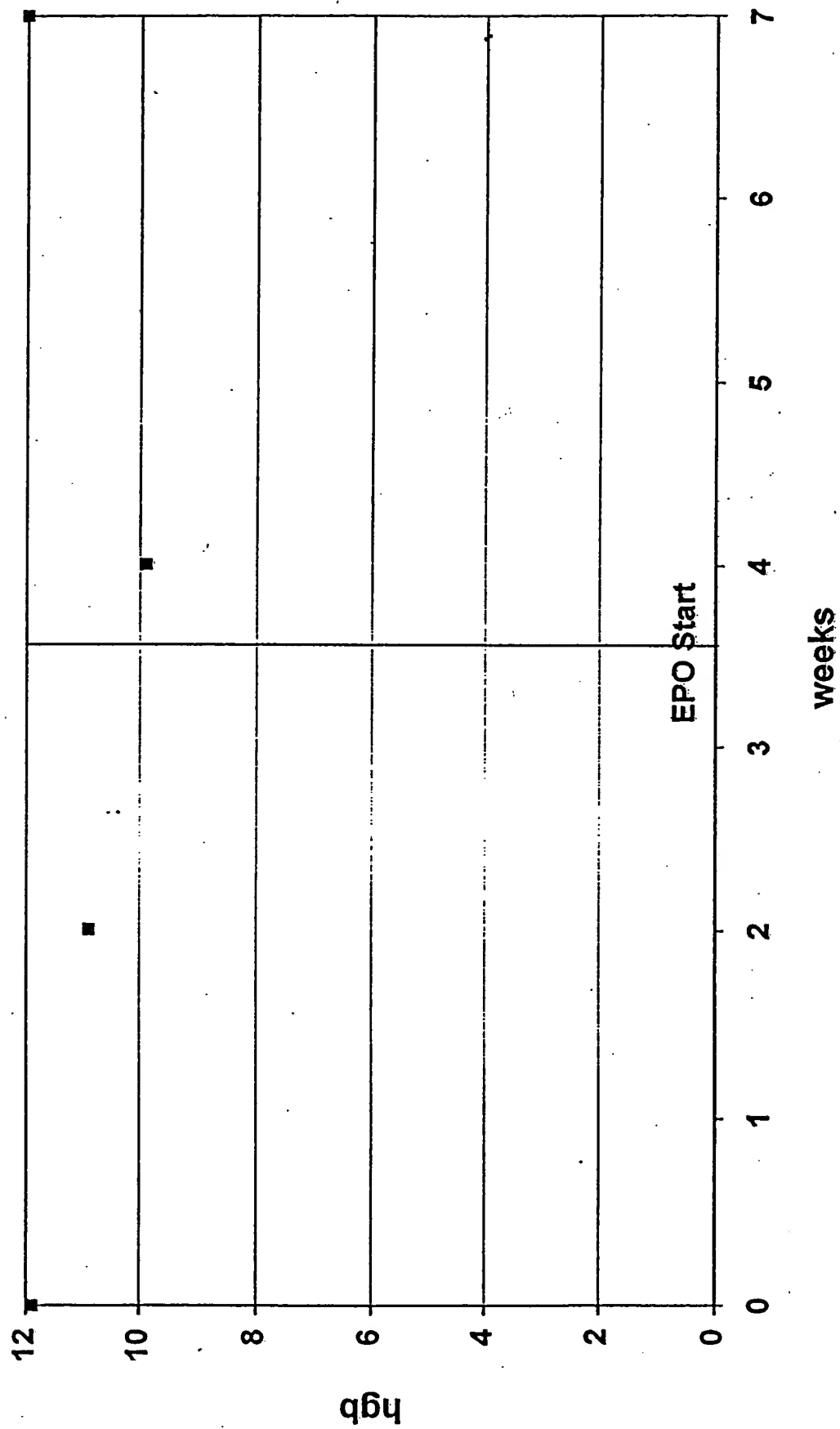
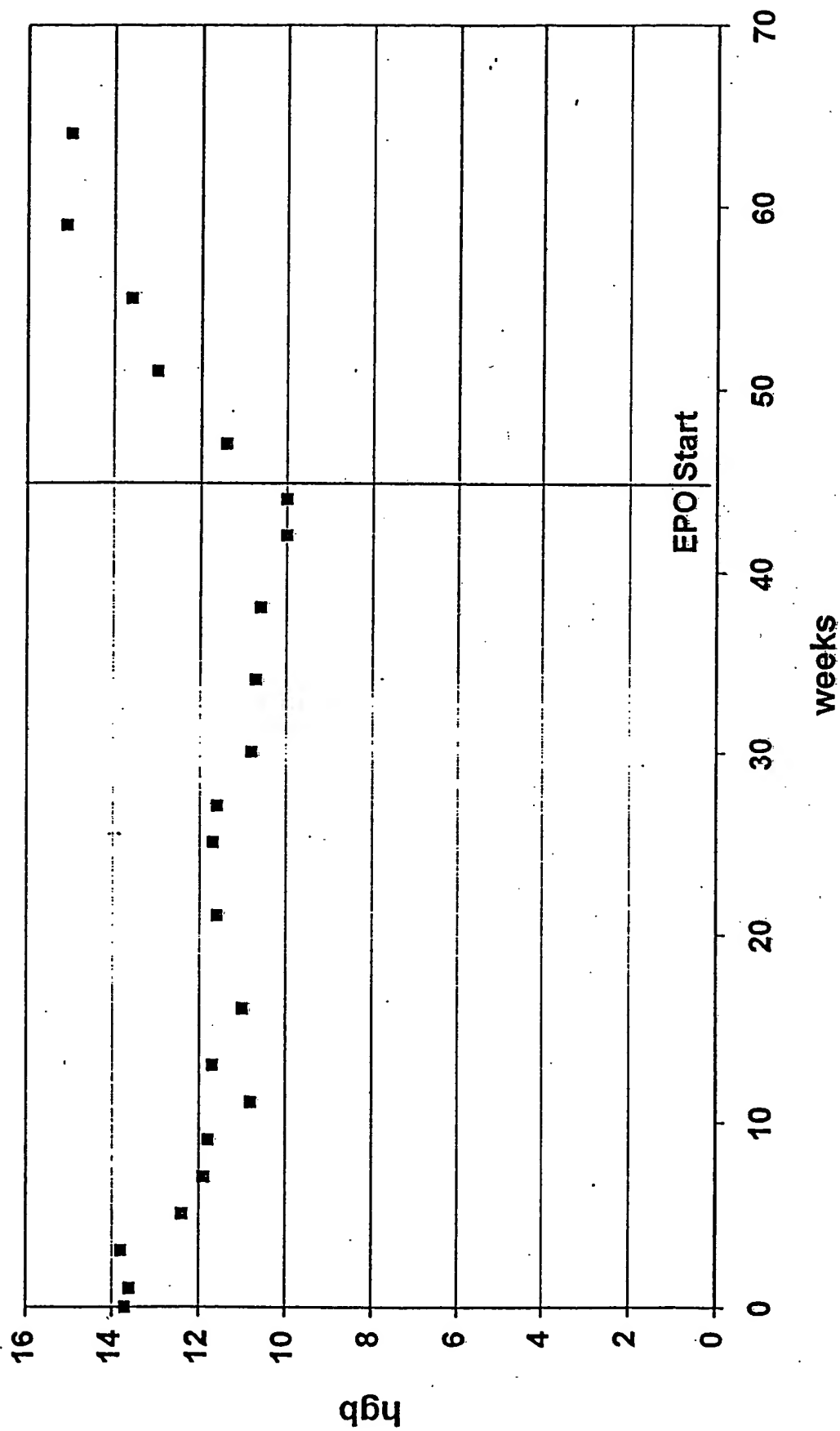


FIGURE 2.16

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# Subject #22

FIGURE 2.17



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# Subject #23

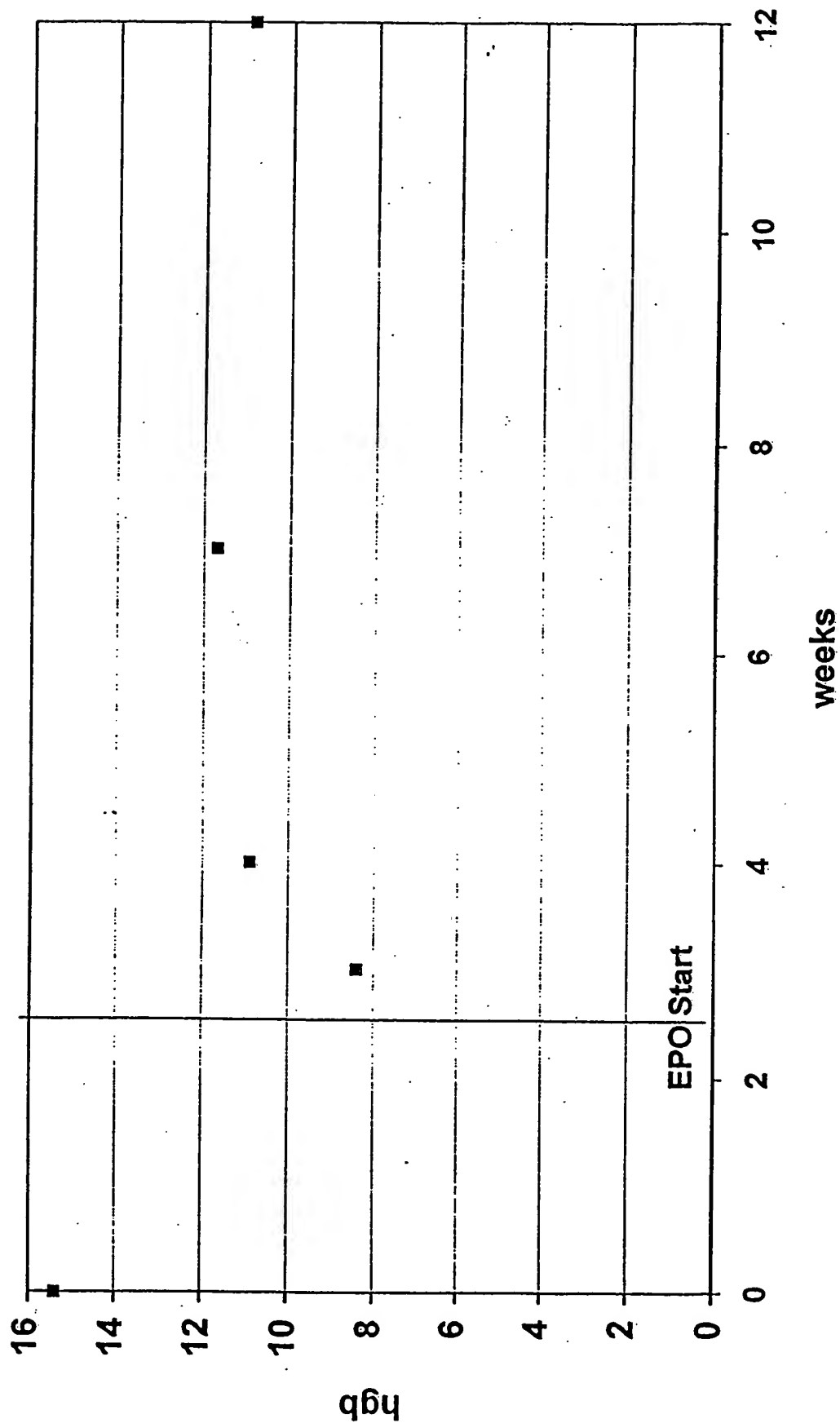


FIGURE 2.18